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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/748,127	12/27/2000	Chunhua Yan	CL000685	4150

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EXAMINER
FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/748,127	Applicant(s) Boyds et al.
	Examiner Christian L. Fronda	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *4-6, 8-11, 13, and 22-30* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *4-6, 8-11, 13, and 22-30* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☒ The proposed drawing correction filed on *May 8, 2001* is: a) ☒ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 4-6, 8-11, 13, and 22-30 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 4-6, 8-11, 13, and 22-30 are again rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicants' arguments filed 12/20/2002 (Paper No.17) have been fully considered but they are not persuasive. Applicants' position is that since the reference Rylander et al. (Biochemical and Biophysical Research Communications 281, 529-535 (2001)) discloses a deduced amino acid sequence of CYP2S1 that is 100% identical to the deduced amino acid sequence of SEQ ID NO: 2 of the instant invention and shows CYP2S1 mRNA transcripts expressed in several tissues, the claimed invention of SEQ ID NO: 2 belongs to the cytochrome 450 family. The Examiner disagrees for the reasons of record and the reasons stated below.

Applicant discloses the nucleotide sequences of SEQ ID NOS: 1 and 3 and the deduced amino acid sequence of SEQ ID NO: 2. Applicants state that based on homology searches that the protein consisting of SEQ ID NO: 2 is a protein related to the cytochrome p450 drug-metabolizing enzyme subfamily which is a generic asserted utility.

The specification does not specifically disclose the function/activity of the protein consisting of SEQ ID NO: 2 or its relationship to any disease. The specification and Rylander et al. reference the does not show any enzyme assays that demonstrate that the claimed protein consisting of SEQ ID NO: 2 or the CYP2S1 protein taught by Rylander et al. has cytochrome p450 activity.

There is no disclosed or "real world" utility associated with the nucleic acid of SEQ ID NO: 1, the nucleic acid of SEQ ID: 3, or the protein of SEQ ID NO: 2. It appears that the main utility of the nucleic acids and protein is to carry out further research to identify the biological function and possible diseases associated with the nucleic acids and protein. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Thus, the

claimed invention has no specific and substantial asserted utility or a well established utility.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 4-6, 8-11, 13, and 22-30 are again rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above in the rejection of the claims under 35 U.S.C. § 101, one skilled in the art clearly would not know how to use the claimed invention.

6. Claim 13 is again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' arguments filed 12/20/2002 (Paper No.17) have been fully considered but they are not persuasive. Applicants' position is that one of skilled in the art would know how to select a 20 mer that is unique to the claimed nucleotide sequence. The Examiner disagrees for the reasons of record and the reasons stated below.

The nature and breadth of the claim encompasses any method for detecting the presence of a nucleic acid molecule in a sample by hybridizing any oligonucleotide probe comprising any 20 contiguous nucleotides that will hybridize to a nucleic acid molecule that encodes a protein comprising the amino acid sequence of SEQ ID NO: 2, the nucleotide sequence of SEQ ID NO: 1, or the nucleotide sequence of SEQ ID NO: 3.

The state of the prior art as exemplified by Wallace et al. and Sambrook et al. is such that determining the specificity of hybridization probes is empirical by nature and the effect of mismatches within an oligonucleotide probe is unpredictable. Therefore, predictability of which 20mer oligonucleotide probe will hybridize specifically and preferentially to a nucleic acid molecule that encodes a protein comprising the amino acid sequence of SEQ ID NO: 2, the nucleotide sequence of SEQ ID NO: 1, or the nucleotide sequence of SEQ ID NO: 3 is extremely low.

The specification does not provide guidance with respect to the specific nucleotide

The specification does not provide guidance with respect to the specific nucleotide sequence of any oligonuleotide probe comprising at least 20 contiguous nucleotides that will specifically and preferentially hybridize to a nucleic acid molecule that encodes a protein comprising the amino acid sequence of SEQ ID NO: 2, the nucleotide sequence of SEQ ID NO: 1, or the nucleotide sequence of SEQ ID NO: 3.

Undue experimentation must be performed and entails performing extensive hybridization experiments with every 20mer oligonucleotide probe possible to determine which 20mer oligonucleotide probe will specifically and preferentially hybridize to a nucleic acid molecule that encodes a protein comprising the amino acid sequence of SEQ ID NO: 2, the nucleotide sequence of SEQ ID NO: 1, or the nucleotide sequence of SEQ ID NO: 3 in a nucleic acid sample.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific nucleotide sequence of the oligonucleotide probe which will specifically and preferentially hybridize to a nucleic acid molecule that encodes a protein comprising the amino acid sequence of SEQ ID NO: 2, the nucleotide sequence of SEQ ID NO: 1, or the nucleotide sequence of SEQ ID NO: 3 in a nucleic acid sample. Without such a guidance, the experimentation left to those skilled in the art is undue.

Conclusion

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. The

Examiner can be contacted Monday-Friday from 8:30AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF